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SUBJECT: INDIA LAUNCHES ITS OFFICIAL CLINICAL TRIALS REGISTRY

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1. (U) Summary. India is rapidly emerging as an attractive destination for clinical research. The need to ensure transparency, accountability and accessibility of clinical trial data has galvanized India to launch its official clinical trials registry. This initiative, christened as the Clinical Trials Registry - India (CTRI), aims to ensure that every clinical trial, conducted in India and involving human participants, of any intervention is prospectively registered. The CTRI's disclosure dataset has been modeled on the recommendations of World Health Organization's International Clinical Trials Registry Platform (WHO ICTRP). India expects CTRI to become an associate member of the WHO ICTRP, transforming it into a regional registry. At present, registration of clinical trials with the CTRI is purely voluntary. With the advent of CTRI, no changes are envisaged for USG and US industry-supported clinical trials that are ongoing. However, registration needs to be considered for all new US supported clinical trials. This is a step towards improving transparency and increasing public trust in the conduct of clinical research.

India's Need to Set Up the CTRI

2. (U) With India rapidly emerging as a strong contender in the global clinical research industry, the need to ensure transparency, accountability and accessibility of clinical trial data has become increasingly significant. Through the initiative of India's Ministry of Health (MOH), the National Institute of Medical Statistics (NIMS) of the Indian Council of Medical Research (ICMR) has set up the CTRI. Commenting on its launch, ICMR's Director General Professor N. K. Ganguly said "with the launch of the CTRI, India is among the select countries such as Australia, the United Kingdom, and the US

that will ensure researchers are accountable through registration and public disclosure of clinical trials."

Bio-Medical Publishing Industry Driving Trial Registration

¶3. (U) Registration of clinical trials is now becoming a pre-requisite for their publication in reputed medical journals. In 2005, the International Committee of Medical Journal Editors (ICMJE) - a group of high profile medical journals - initiated a policy that its journals would not accept papers reporting clinical studies that had not been included in an authorized register before the onset of patient enrollment. Subsequently, several other medical journals have adopted this policy. Through the CTRI launch, India looks to comply with this requirement and thus strengthen the publishing ability of its clinical researchers.

Funding for CTRI

¶4. (U) NIMS has set up the CTRI with funding support from the GOI's Department of Science and Technology (DST) through the ICMR. The CTRI also receives financial and technical support through the WHO, WHO South-East Asia Regional Office (WHO SEARO), and the WHO India Country office.

Important Aspects of the CTRI

¶5. (U) India in its official communication states that the CTRI aims to ensure that every clinical trial, conducted in India and involving human participants, of any intervention (drug, surgical procedure, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies and complementary therapies) is prospectively registered (that is,

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before the enrollment of the first patient).

¶6. (U) At present, registration of clinical trials with the CTRI is free and purely voluntary. Besides the 20 items recommended by the WHO International Clinical Trials Registry (WHO ICTRP), a prospective registrant is also required to disclose information regarding a few additional India-specific items, such regulatory clearance from Drugs Controller General of India (DCGI), name of ethics committee and approval status, etc. The CTRI will encourage regular updates from registrants on protocol amendments and trial status.

¶7. (U) It is being hoped that CTRI will serve as a primary registry for the WHO ICTRP. It will collect disclosure dataset on all clinical trials to be undertaken in India and make this information available to the public. The plan is to make the CTRI a freely available and a searchable primary registry.

CTRI Hopes to Become a Regional Player

¶8. (U) India expects CTRI to become an associate member of the WHO ICTRP, transforming it from a national to a regional registry. India will allow researchers from neighboring countries such as Sri Lanka, Nepal, Bangladesh, Bhutan and Pakistan to register their trials with the CTRI.

India Makes no Mention of US Registry Initiatives

¶9. (SBU) Interestingly, India has adopted clinical trial disclosure dataset in line with WHO recommendations. This is despite the fact that ClinicalTrials.gov has been the first initiative ever where clinical trials could be registered. This was developed by NIH's National Library of Medicine (NLM). Over the years, ClinicalTrials.gov and other registries have been providing updated information about research in human volunteers, for both federally and privately supported clinical trials. US-India bilateral collaboration has included a series of workshops on clinical

research aimed to update skill-sets in this sunshine area. This series is ongoing with funding by the NIH Office of AIDS Research (OAR). In October 2006, the technical architect of ClinicalTrials.gov, NLM, Nick Ide made a presentation in India as a part of this collaboration. (Note: India has always been edgy on being associated in print on good ideas derived from US initiatives. End Note.)

Pharmaceutical and Biotech Industry Apprehensions

¶10. (U) Pharmaceutical and biotech industry has suggested that a so-called "lockbox" provision be included for certain registration data items. This will serve to block access to information that industry considers proprietary and that would be divulged through public disclosure. In general, the industry would like to defer public disclosure of certain details, such as description of the intervention, target sample size, and primary and key secondary outcomes, until the product is approved for the intended indication.

Implications for USG and US Industry-Supported Trials

¶11. (U) With the setting up of the CTRI, no changes are envisaged for USG and US industry-supported clinical trials that are ongoing. However, CTRI registration needs to be considered for all new US

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supported clinical trials.

¶12. (U) The advent of CTRI and the public accessibility to clinical trial data should promote greater public confidence in clinical trials in India.

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